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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,008	12/22/2000	Christian Viskov	03806.0488-00000	7790
22852 7590 04/26/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER KAM, CHIH MIN	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 04/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Supplemental  
Notice of Allowability**

Application No.

09/742,008

Examiner

Chih-Min Kam

Applicant(s)

VISKOV, CHRISTIAN

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/14/06.
2. ☒ The allowed claim(s) is/are 1,5-13,23 and 24.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 12/22/00
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

**DETAILED ACTION*****Supplemental Examiner's Amendment***

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

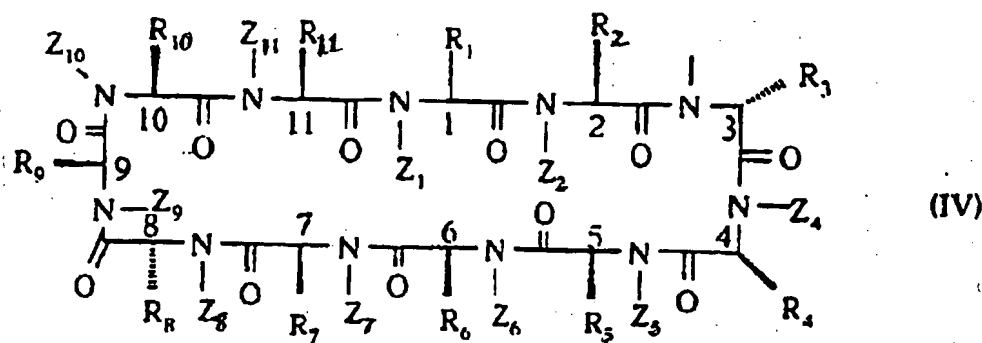
Authorization for this examiner's amendment was given in a telephone interview with Aaron Raphael on April 25, 2007.

**Examiner's Amendment to the Claims:**

Please cancel claims 15-21.

Claim 13 has been amended as follows:

13. (Currently amended) A process for preparing a cyclosporin derivative substituted at the 3-position, said process comprising preparing a polyanion by treating a cyclosporin with a hexamethyldisilazane metal salt, optionally in the presence of a metal halide, wherein the treatment of the cyclosporin is carried out at a temperature ranging from -40°C to 0°C, adding an electrophilic agent to said treated cyclosporin, and, optionally converting the product of said addition to a salt, in which at least one obtained cyclosporin derivative substituted at the 3-position has the formula:



in which

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the radicals  $R_1$ ,  $R_2$ , and  $R_4$  to  $R_{11}$ , and  $Z_1$ ,  $Z_2$ , and  $Z_4$  to  $Z_{11}$  are defined as for cyclosporin A, with the exception of  $R_4$  and  $Z_4$ , which are defined so as to have, at the 4-position, the amino acid 4'-hydroxy-methylleucine, and of  $R_3$ , which is  $-S-OH_3$ ,  $-S-CH_3$  or a radical  $-S-Alk-R^\circ$  in which:

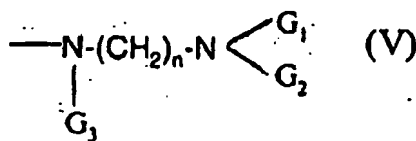
Alk is an alkylene radical comprising from 2 to 6 straight- or branched-chain carbon atoms or a cycloalkylene radical comprising from 3 to 6 carbon atoms;

and

$R^\circ$  is

a hydroxyl, carboxyl, or alkyloxycarbonyl radical; or

an  $-NG_1G_2$  radical or a radical of formula:



in which  $G_1$  and  $G_2$ , which are identical or different, are each a hydrogen atom; or

a phenyl, cycloalkyl ( $C_{3-6}$ ), alkenyl ( $C_{2-4}$ ), or alkyl radical, each of which is optionally substituted by a halogen atom, an alkyloxy, alkyloxycarbonyl, amino, alkylamino, or dialkylamino radical; or

a benzyl radical or a saturated or unsaturated heterocyclyl radical comprising 5 or 6 ring members and from 1 to 3 heteroatoms; or

$G_1$  and  $G_2$  form, with the nitrogen atom to which they are attached, a saturated or unsaturated heterocycle comprising from 4 to 6 ring members which can comprise another heteroatom chosen from nitrogen, oxygen,

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and sulphur and which is optionally substituted by alkyl, phenyl, or benzyl;

and

G<sub>3</sub> is a hydrogen atom or an alkyl radical, and n is an integer from 2 to 4,

the alkyl portions or radicals defined above are straight or branched and

comprise from 1 to 4 carbon atoms.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK  
April 25, 2007